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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/692,063	10/23/2003	David F. Davenport	03880-P0002B	7269

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EXAMINER	
ARNOLD, ERNST V	

ART UNIT	PAPER NUMBER
1616	

DATE MAILED: 06/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/692,063	DAVENPORT ET AL.	
	Examiner	Art Unit	
	Ernst V. Arnold	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *25-48,50 and 51* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *25-48,50 and 51* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *08/29/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The Examiner acknowledges receipt of application number 10/692,063 filed on 10/23/2003 and claims benefit of 60/420,548 filed on 10/23/2002. In response to the restriction requirement, Applicant has elected without traverse Group II, claims 25-48 and cancelled claims 1-24 and 49. Applicant has added new claims 50 and 51. Accordingly, claims 25-48, 50 and 51 are pending in the application.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 25, 27-34, 36, 38, 50 and 51 are rejected under 35 U.S.C. 102(b) as being anticipated by Berk et al. (US 6,017,550).

Berk et al. disclose a method of enteral administrating to a human in need of treatment a low viscosity liquid nutritional formula (Claim 14). Berk et al. disclose in the specification a nutritional formula:

TABLE I

Approximate Composition of FIBRIM 300 ®

Nutrient	FIBRIM 300 ® per 100 g
Protein	11.6 g
Fat	1.0 g
Carbohydrate	71.0 g
Ash	6.5 g
Moisture	6.5 g
Calcium	440. mg
Phosphorous	330. mg
Magnesium	220. mg
Sodium	250. mg
Potassium	870. mg
Chloride	170. mg
Iron	12.0 mg
Zinc	2.2 mg
Copper	0.26 mg
Thiamin	0.09 mg
Riboflavin	0.22 mg
Pyridoxine	0.008 mg
Niacin	0.093 mg
Folic Acid	5.47 mcg
Pantothenic Acid	0.017 mg
Biotin	0.054 mg
Choline	85. mg
Inositol	121. mg
Dietary Fiber	78.2 g

(Column 10, lines 10-33). The Examiner calculates that the composition contains less than 3% fat, only 1 g in about 177 g, which corresponds to about 0.56%, and an effective proportion of components thus meeting the limitations of instant claims 25, 27, 28, 29, 30, 32, 33, 34, 36, 50 and 51. It is the Examiner's position that administration of composition disclosed by Berk et al. to a subject would inherently provide calories for energy. In addition, the liquid composition would contain dissolved vitamins and thus read on instant claim 28. Berk et al. disclose that the formula can additional comprise fat, carbohydrates, vitamins and minerals (Claim 16). Berk et al. disclose that the source of amino nitrogen is selected from amino acids and hydrolyzed whey, for example, thus reading on instant claim 38 (Claim 17). Berk et al. disclose that the fiber blend is a

mixture of hydrolyzed carboxymethylcellulose and at least one fiber selected from oat hull fiber and oat glucans, for example, thus reading on instant claim 31 (Claim 18).

Claim Rejections - 35 USC § 102

Claims 25-30, 32-37, 43, 44, 47, 50 and 51 are rejected under 35 U.S.C. 102(b) as being anticipated by Paul et al. (US 5,292,538).

Paul et al. disclose a method of providing sustained energy and nutrition in a human comprising administering to said human an effective amount of (a) from 25 to 100 parts of glucose polymers; (b) from 5 to 20 parts of fructose; (c) from 5 to 25 parts f a hydrolyzed protein; (d) from 0 to 20 parts of a lipid source and (e) from 50 to 500 × 10-3 parts of magnesium and from 0.03 to 6 parts of amino acid ligand source wherein the magnesium is present as an amino acid chelate (Claims 13-25). The method of Paul et al. thus embraces a fat content of less than 3% and the range of about 2 to about 2.5% of instant claims 25 and 26. Paul et al. provide eight formulations shown below reading on instant claims 27, 29, 30, 34-37, 43, 44 and 47 (Column 10 line 57-column 11, line 35).

INGREDIENTS	FORMULATION NUMBER I	II	III	IV	V	VI	VII	VIII
Glucose Polymers (g)	62.1	75.0	60.0	50.0	100.0	60.0	55.0	25.0
Crystalline Fructose (g)	11.0	15.0	10.0	8.0	20.0	10.0	12.0	5.0
Lactalbumin (g)	13.5	20.0	5.0	25.0	20.0	12.0	15.0	10.0
Lipid (g)	1.3	4.0	—	5.0	—	0.6	2.0	—
Magnesium (mg)	160.3	*500.0	*110.2	*183.0	155.0	*145.8	170.0	64.5
Amino Acid Lig (mg)	[a]990.0	[b]5200.0	[c]996.0	*1130.0	[d]1920.0	[e]1560.0	[f]1260.0	[a]398.0
Potassium (mg)	282.1	360.0	100.0	330.0	—	—	300.0	200.0
Phosphorus (mg)	160.3	180.0	50.0	140.0	—	—	160.0	100.0
Manganese (mg)	[1]1.3	[1]1.5	0.5	1.0	—	—	[1]1.4	[1]1.5
Zinc (mg)	[2]3.2	[2]2.1	1.0	1.0	—	—	[2]2.4	[2]5.0

INGREDIENTS	FORMULATION NUMBER I	II	III	IV	V	VI	VII	VIII
Iron (mg)	[3]1.9	[3]2.1	1.0	1.0	—	—	[3]2.4	[3]5.0
Boron (mg)	[4]1.0	[4]1.0	—	0.5	—	—	[4]0.8	[4]1.5
Copper (µg)	[5]320.5	[5]200.0	350.0	380.0	—	—	[5]300.0	[5]260.0
Molybdenum (µg)	[6]6.4	[6]2.1	6.0	4.8	—	—	[6]4.4	[6]7.0
Chromium (µg)	[7]128.2	[7]150.0	[8]100.0	190.0	—	—	[7]140.0	[7]156.0
L-Carnitine (mg)	32.1	—	48.0	—	—	20.0	20.0	93.0
Vanadyl Sulfate (µg)	6.4	10.0	3.0	—	—	3.0	7.3	10.0
Pyr. α-Ketoglutarate (mg)	32.1	160.0	35.0	—	—	30.0	28.0	13.0
Inosine (mg)	64.1	85.0	25.0	—	—	70.0	75.0	30.0
Vitamin A (IU)	1602.6	1500.0	—	1450.0	—	—	2000.0	1250.0
Vitamin B1 (mg)	1.0	1.8	—	1.0	—	—	1.0	1.5
Vitamin B2 (mg)	1.2	1.5	—	1.0	—	—	1.0	2.0
Vitamin B5 (mg)	32.1	30.0	—	50.0	—	—	25.0	42.0
Vitamin B6 (mg)	1.3	1.5	—	1.0	—	—	1.0	0.8
Vitamin B12 (µg)	3.8	4.0	—	2.9	—	—	3.5	4.3
Vitamin D (IU)	128.2	164.0	—	164.0	—	—	120.0	100.0
Folic Acid (µg)	256.4	244.0	—	310.0	—	—	240.0	227.0
Niacinamide (mg)	6.4	4.0	—	7.0	—	—	4.0	5.0
Biotin (mg)	192.3	225.0	—	175.0	—	—	180.0	203.0
B-Carotene (IU)	1602.6	1500.0	—	—	—	—	2000.0	1250.0
Vitamin E (IU)	19.2	15.0	—	—	—	—	25.0	18.0
Selenium (µg)	[9]16.0	14.0	—	—	—	—	20.0	18.0
N-Acetyl Cysteine (mg)	64.1	88.0	—	—	—	—	130.0	130.0
Lipoic Acid (µg)	64.1	88.0	—	—	—	—	56.0	80.0
Vitamin C (mg)	19.2	15.0	—	—	—	—	25.0	53.0
Choline (mg)	64.1	55.0	—	73.0	—	—	70.0	48.0
Inositol (mg)	64.1	55.0	—	73.0	—	—	74.0	63.0
Pantetheine (mg)	32.1	60.0	—	22.0	—	—	45.0	23.0
Betaine HCL (mg)	64.1	70.0	—	53.0	—	—	81.0	59.0

[1]= manganese arginate
[2]= zinc arginate
[3]= iron glycinate
[4]= boron citrate aspartate glycinate
[5]= copper glycinate
[6]= molybdenum aspartate
[7]= chromium nicotinate glycinate
[8]= chromium glycinate
[9]=selenomethionine
*= as a pharmaceutical grade chelate
[a]= glycine
[b]= hydrolyzed protein isolate ave m.w. 125
[c]= mixed amino acids ave m.w. 110
[d]= enzymatic hydrolyzed soy ave m.w. 150
[e]= hydrolyzed casein ave m.w. 130
[f]= mixed amino acids ave m.w. 90

Paul et al. disclose that the formulation can be manufactured in a powder form and mixed with water for consumption or formulated as a liquid (Column 8, lines 36-45). It is the Examiner's position that consumption of the liquid formulations of Paul et al. is enteric administration.

Claim Rejections - 35 USC § 102

Claims 25, 44, 48, 50 and 51 are rejected under 35 U.S.C. 102(b) as being anticipated by Hsia (US 6,294,166).

Hsia discloses a method of improving the health of a mammal comprising orally administrating viable lactobacillus acidophilus bacteria (a probiotic), non-living yeast and protein from whey or soy isolates (Abstract and claim 1). The amount of bacteria ranges from about 0.1 to about 10% of the total mass of the composition (Column 4, lines 53-56). The amount of yeast is from about 2.5% to about 20% of the total mass of the composition (Column 5, lines 1-2). The amount of protein is from about 25% to about 98% of the total mass of the compositions (Column 5, lines 6-16). It is the Examiner's position that administration of composition disclosed by Hsia to a subject would inherently provide calories for energy. Since the method of Hsia does not include fats or lipids and the ingredients are in an effective proportion it then meets the limitation of instant claims 25, 44, 48, 50 and 51.

Claim Rejections - 35 USC § 102

Claims 25, 44, 45, 50 and 51 are rejected under 35 U.S.C. 102(b) as being anticipated by Murad (US 5,804,594).

Murad discloses tablets containing N-acetylglucosamine and D-glucosamine sulfate with only 0.1% w/w coconut oil (Column 10 line 35-column 11 line 10). Murad discloses a method of administering the 2 tablets to 73 female subjects daily with meals for the prevention or treatment of skin conditions (Column 11, lines 44-46 and claims 13-19). It is the Examiner's position that administration of composition disclosed by Murad to a subject would inherently provide calories for energy and read upon instant claim 25.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 25, 26, and 41-44, and 46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Berk et al. (US 6,017,550).

Applicant claims a method for reducing the energy deficit in a mammal comprising the step of enterically administering to the mammal an energy promoting effective amount of a composition having less than 3% fat comprising an effective proportion of components.

Determination of the scope and content of the prior art

(MPEP 2141.01)

The reference of Berk et al. is discussed in detail above and that discussion is hereby incorporated by reference.

Ascertainment of the difference between the prior art and the claims

(MPEP 2141.02)

1. Berk et al. do not expressly teach a composition that comprises between about 2% to about 2.5% by weight fat.

2. Berk et al. do not expressly teach a composition that further comprises at least one monosaccharide wherein the monosaccharide is selected from the group consisting of glucose, galactose, fructose and combinations thereof.

3. Berk et al. do not expressly teach a composition comprising at least one amino acid.

4. Berk et al. do not expressly teach a composition comprising glucosamine, salt, amino acid, yeast, fermentation extract and combinations thereof.

Finding of prima facie obviousness

Rational and Motivation (MPEP 2142-2143)

1. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to use a composition that comprises between about 2% to about 2.5% by weight fat in the method of Berk et al. and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because Berk et al. teach different ranges for the fat content from about 0.56, as discussed above, to about 5% (Column 11, Table II; Column 12, Table III and column 12, line 42-column 13, line 10). The determination of the best fat percentage in the composition is deemed merely a matter of routine optimization by one of ordinary skill in the art.

2-4. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to add amino acids such as cystine, tryptophan and tyrosine; monosaccharides such as sucrose; salts such as sodium chloride; and carnitine because Berk et al. teaches a composition with these ingredients (column 12, line 42-column 13, line 10).

One of ordinary skill in the art would have been motivated to do this because Berk et al. teach the inclusion of these ingredients in the composition for use in the method. The teachings of Berk et al. render obvious other monosaccharides, minerals, salts and amino acids to one of ordinary skill in the art.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Claim Rejections - 35 USC § 103

Claims 25 and 38-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schlothauer et al. (WO 99/65326).

Applicant claims a method for reducing the energy deficit in a mammal comprising the step of enterically administering to the mammal an energy promoting effective amount of a composition having less than 3% fat comprising an effective proportion of components wherein the composition comprises at least one ingredient selected from the group consisting of whey powder, lactase and combinations thereof.

Determination of the scope and content of the prior art

(MPEP 2141.01)

Schlothauer et al. teach bioactive whey protein hydrolysate that has a mean particle size of less than about 30 microns (Abstract; and claim 22). Schlothauer et al. teach a process to remove residual lactose by treatment with lactase either before, during or after whey protein hydrolysis (Claim 18). Schlothauer et al. teach a food product containing the whey hydrolysate and a method of reducing blood pressure in a subject which comprises administration to that subject an effective amount of the whey product (Claims 28, 30 and 31). Schlothauer et al. teach the amount of lactase to use is from 0.3% (enzyme to substrate ratio (page 9, lines 1-2) to 0.4 % w/w (page 12, lines 14-15). Schlothauer et al. do not add fat to their composition.

Ascertainment of the difference between the prior art and the claims

(MPEP 2141.02)

1. Schlothauer et al. do not expressly teach a method for reducing the energy deficit in a mammal comprising the step of enterically administering to the mammal an energy promoting effective amount of a composition having less than 3% fat comprising an effective proportion of components wherein the composition comprises at least one ingredient selected from the group consisting of whey powder, lactase and combinations thereof.

2. Schlothauer et al. do not expressly teach a method wherein the composition comprises between about 95% to about 100% by weight whey powder and between about 1% to about 5% by weight lactase.

Finding of prima facie obviousness

Rational and Motivation (MPEP 2142-2143)

1 and 2. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to make a food product containing lactase and whey and administer it to a subject as taught by Schlothauer et al. It is the Examiner's position that the administration of a nutritional drink will introduce calories into the subject and therefore reduce the energy deficit. It is an intrinsic aspect of the method.

One of ordinary skill in the art would have been motivated to do this because Schlothauer et al. teach that a nutritional whey protein drink has the health advantages of whey protein. The determination of the amount of lactase to be added to the whey is

deemed merely a matter of routine optimization, which one of ordinary skill in the art can perform during ordinary laboratory experimentation.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

37 CFR 1.105

Applicant and the assignee of this application are required under 37 CFR 1.105 to provide the following information that the examiner has determined is reasonably necessary to the examination of this application.

An issue of public use or on sale activity has been raised in this application. In order for the examiner to properly consider patentability of the claimed invention under 35 U.S.C. 102(b), additional information regarding this issue is required as follows: All documentation relevant to the prosecution of the instant application concerning the public sale and knowledge of the invention is requested. The information submitted by Applicant includes marketing material with phone numbers and a website which raises the question to the Examiner as to exactly when the product was made available to the public.

Applicant is reminded that failure to fully reply to this requirement for information will result in a holding of abandonment.

In responding to those requirements that require copies of documents, where the document is a bound text or a single article over 50 pages, the requirement may be met by providing copies of those pages that provide the particular subject matter indicated in the requirement, or where such subject matter is not indicated, the subject matter found in applicant's disclosure.

The applicant is reminded that the reply to this requirement must be made with candor and good faith under 37 CFR 1.56. Where the applicant does not have or cannot readily obtain an item of required information, a statement that the item is unknown or cannot be readily obtained may be accepted as a complete reply to the requirement for that item.

This Office action has an attached requirement for information under 37 CFR 1.105. A complete reply to this Office action must include a complete reply to the attached requirement for information. The time period for reply to the attached requirement coincides with the time period for reply to this Office action.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

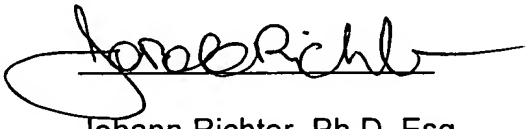
No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ernst V. Arnold whose telephone number is 571-272-8509. The examiner can normally be reached on M-F (6:15 am-3:45 pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ernst Arnold
Patent Examiner
Technology Center 1600
Art Unit 1616
May 02, 2006



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